Welcome to today's
FDA/CDRH Webinar

Thank you for your patience while we register all of today's participants.

If you have not connected to the audio portion of the webinar, please do so now:
Dial: 1-800-369-3195
International Callers: 1-517-308-9090
Passcode: CDRH

Getting Ready for GUDID

January 14, 2015

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FDA\CDRH\OSB\Informatics Staff

UDI = Unique Device Identifier

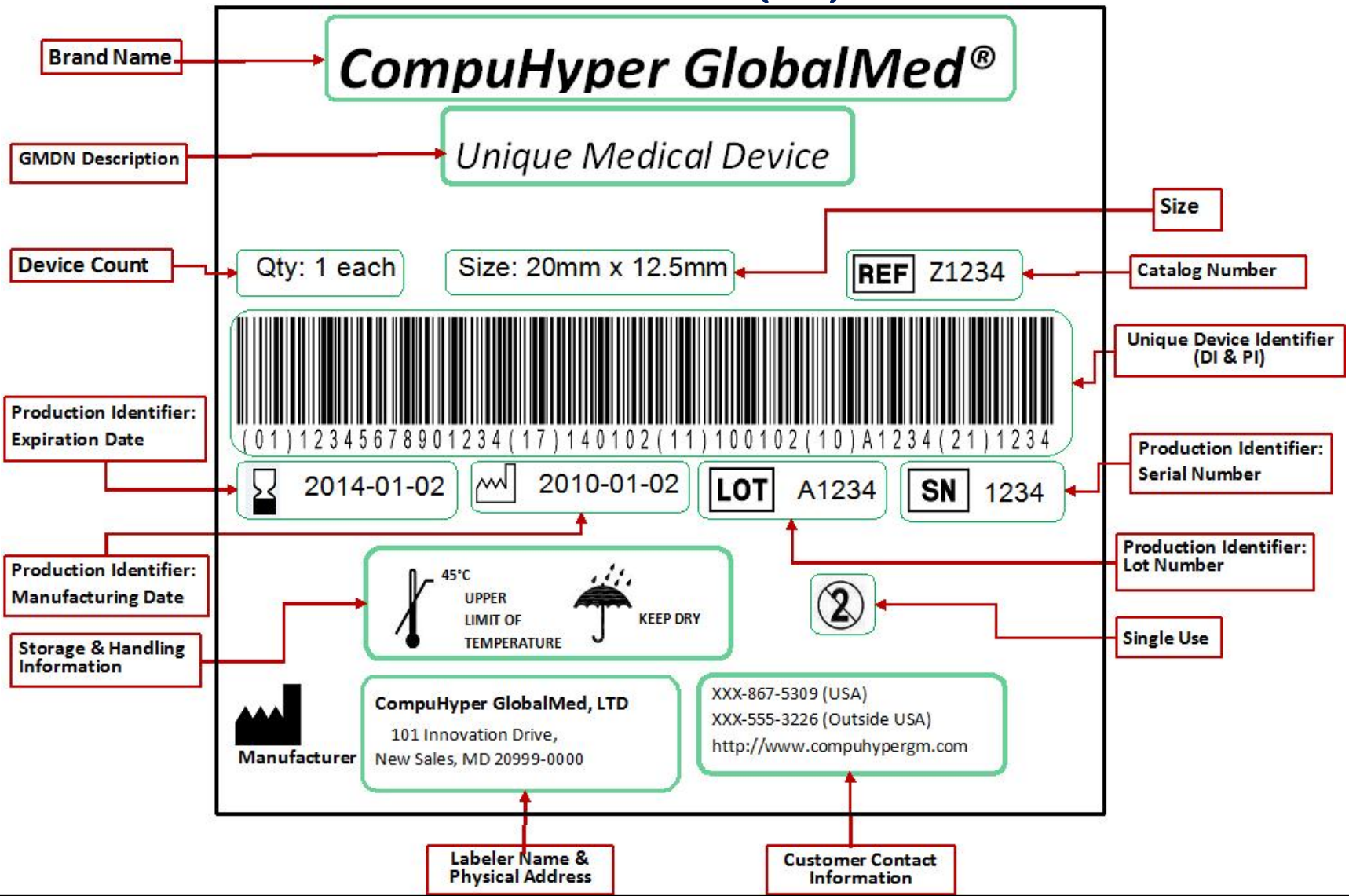
- **Device Identifier(DI) + Production Identifier(s)(PI)**
- **DI= mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device**
- **PI= a conditional, variable portion of a UDI that identifies one or more of the following when included on the label:**
  - Lot or batch number
  - Serial number
  - Expiration date
  - Manufacturing date
  - For an HCT/P regulated as a device, the distinct identification code

GUDID Global Unique Device Identification Database

- **Repository of key device identification information**
- **Contains ONLY the DI; PIs are not submitted to or stored in the GUDID**
  - Contains only PI flags to indicate which PI attribute(s) are in the UDI

DI Record

DI Record = Device Identifier (DI) + GUDID attributes



Device Information

Device Identifier (DI) Information

Issuing Agency: *	Primary DI Number: *	Device Count: *	Unit of Use DI Number:
HIBCC	wsDIOverview	1	

Labeler DUNS Number: *	Company Name:	Company Physical Address:
039169488	Safeway Grocery	4551 Forbes Blvd, Lanham, MD 207064389

Brand Name: *	Version or Model Number: *	Catalog Number:
DIOverview	123456	123456

Device Description (max 2000 characters):

DIOverviewRecord

Commercial Distribution

DI Record Publish Date (yyyy-mm-dd): *	Commercial Distribution End Date (yyyy-mm-dd):	Commercial Distribution Status:
2014-05-09		In Commercial Distribution

Device Characteristics

For Single-Use: * Yes

Production Identifier(s) on Label

Lot or Batch Number: * Yes

Serial Number: * No

Expiration Date: * Yes

Manufacturing Date: * No

Donation Identification Number: * No

Latex Information

Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437): *

No

☐ Device labeled as "Not made with natural rubber latex"

Prescription Status

☑ Prescription Use (Rx)

☑ Over the Counter (OTC)

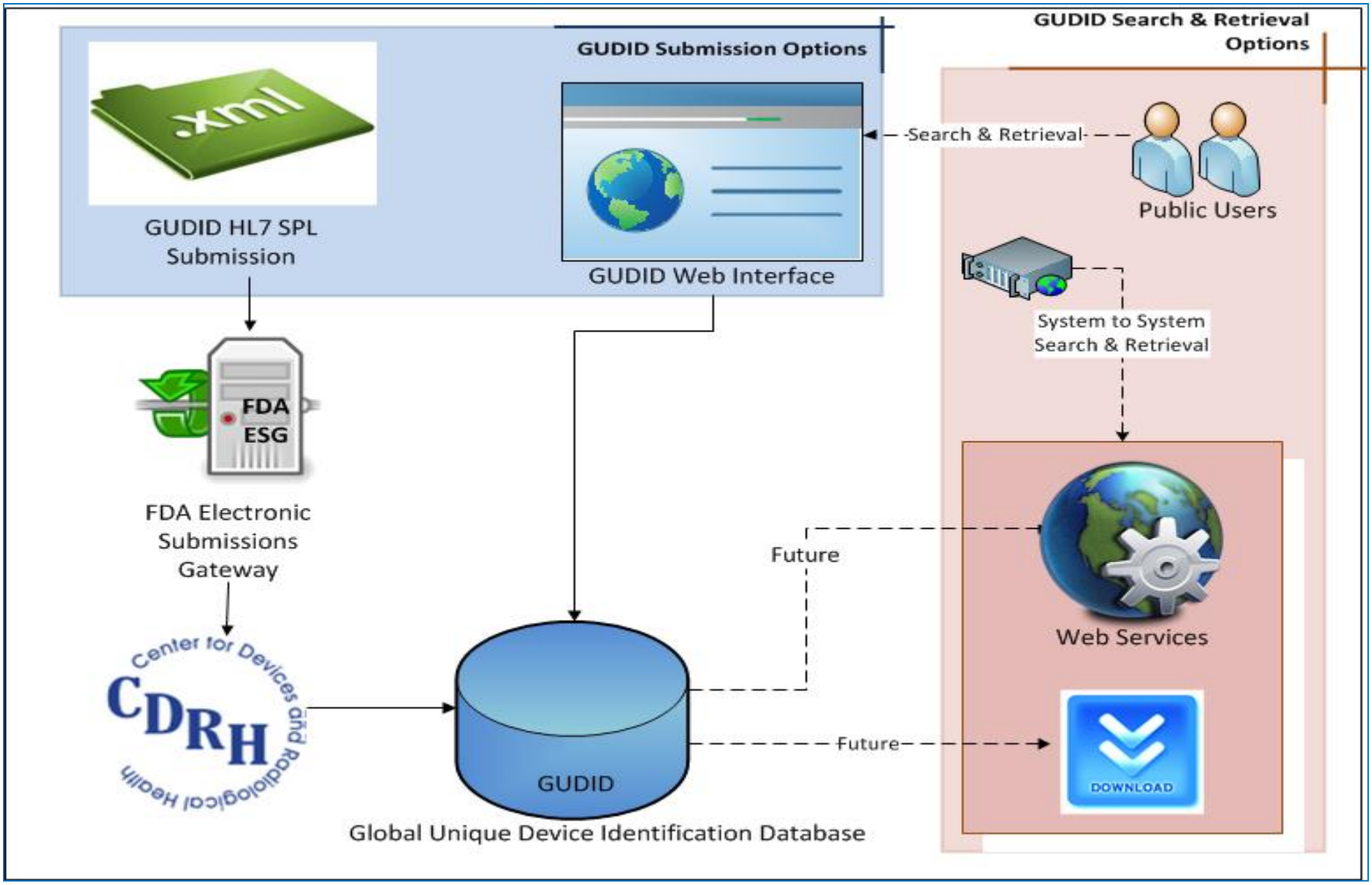
MRI Safety

What MRI safety information does the labeling contain?: *

Labeling does not contain MRI Safety Information

MR Safe
MR Unsafe
MR Conditional
Labeling does not contain MRI Safety Information

GUDID Overview



GUDID Web Interface

GUDID Web Interface

- Secure Web Application
- Submission of device information one record at a time by Labelers

GUDID HL7 SPL Submission Option

- HL7 = Health Level 7
- SPL = Structured Product Labeling
- Submission of device information as xml files – one record per file
- Technical specifications available on the UDI website
- Uses the FDA Electronic Submissions Gateway (ESG) to transmit the file www.fda.gov/esg
- Testing required prior to production submission

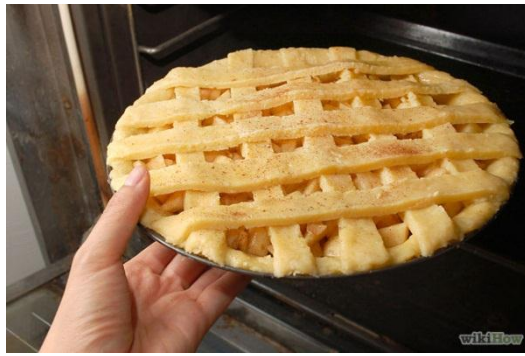
GUDID Search and Retrieval

- **Working with the National Library of Medicine (NLM) to provide:**
  - Public Search
  - Database Download
  - Web Services (future)
- **Releasable attributes of Published DI records will be available**
- **Targeting Spring 2015 for availability**

GUDID and Data Quality

- **Key component of the UDI program**
  - Ready to provide assistance and work collaboratively with labelers
  - Use lessons learned for program and database improvements; refine instructions

- **"Bake-in" Data Quality as you work on GUDID**



Preparing for GUDID

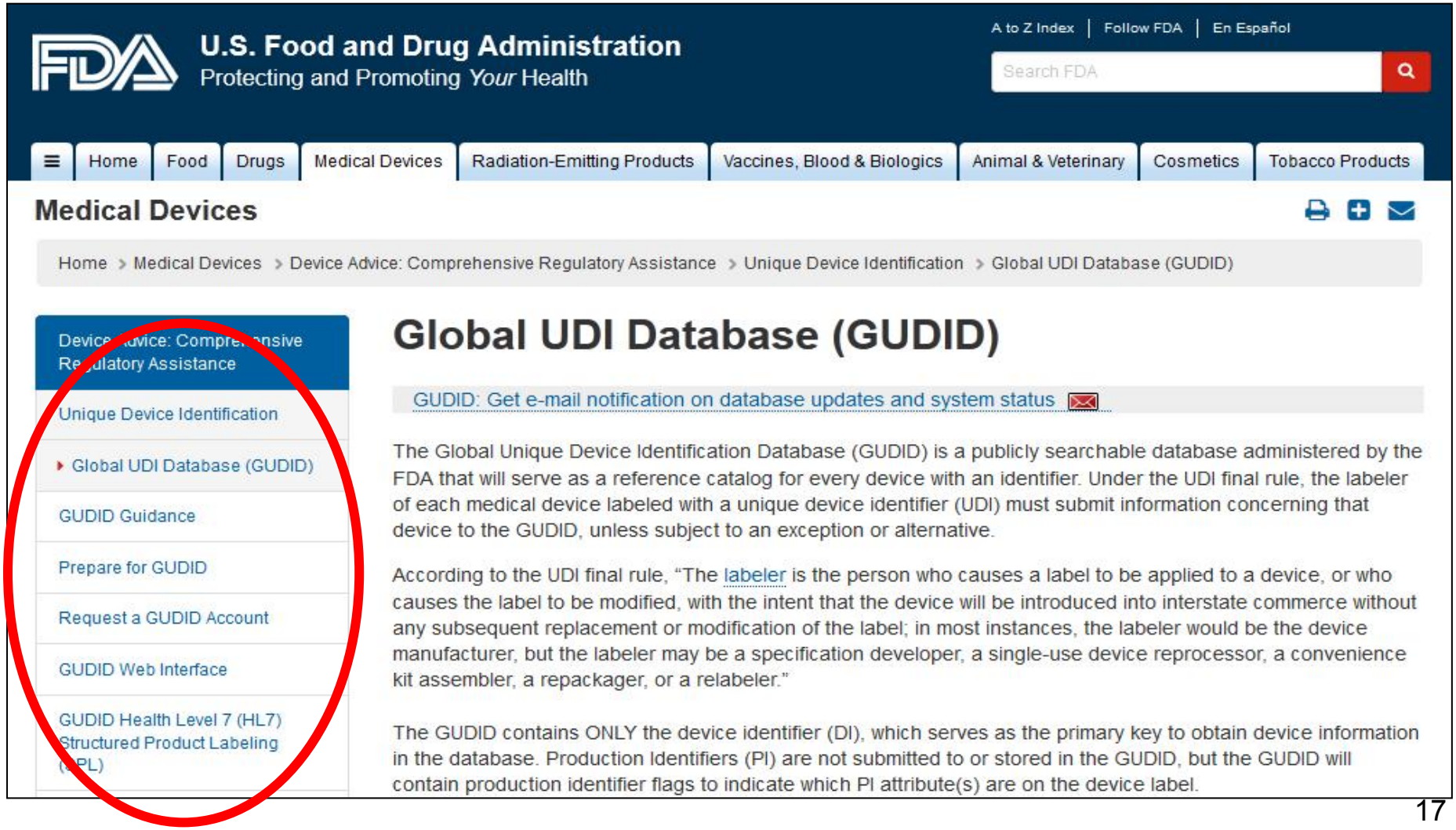
1) Review resources on the UDI Website
2) Select Issuing Agency and label your devices with UDI
3) Determine primary submission option
4) Gather your data
5) Understand the GUDID Account Structure
6) Identify/Obtain DUNS numbers
7) GUDID Web Interface Submitters - TO DO
8) GUDID HL7 SPL Submitters - TO DO
9) Subscribe to get notified about GUDID System Status

1) Review Resources on our website: www.fda.gov/udi

Start with UDI Basics section – what is a UDI, who is a Labeler

Look at UDI Resources for Final Rule, GUDID Guidance, FAQs, training

Review the GUDID section



Review the GUDID section

- Must read!
- What you should do now
- How to request a GUDID Account
- GUDID User Manual
- GUDID HL7 SPL Technical Specification Files
- GUDID System Status Information
- GUDID Enhancements & Fixes Info

Review the GUDID Resources section

GUDID Resources

- CDRH Learn with GUDID Overview
- Guidance - Global Unique Device Identification Database (GUDID) - June 27, 2014 (PDF - 2.8MB)
- HL7 SPL Implementation Files (ZIP - 1.5MB)
- FDA Webinar: Global Unique Device Identification Database (GUDID) Account Set Up
- GUDID Data Elements Reference Table - May 7, 2014 (XLS - 91KB)
- UDI Formats by FDA-Accredited Issuing Agency May 7, 2014 (DOC - 132KB)
- GUDID User Manual -- May 2014 (PDF - 2.2MB)

GUDID Data Elements Reference Table

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Device Information							
Device Identifier (DI) Information							
Issuing Agency	Organization accredited by FDA to operate a system for the issuance of UDIs.	Choose a value from the drop down LOV.	None	Required	NA	GS1; HIBCC; ICCBBA	YES
Primary DI Number	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest package level of a medical device containing a full UDI. For medical devices without packaging, the primary DI number and full UDI may be on the device itself.	Enter the Device Identifier (DI) Number. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters	None	Required	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	NA	YES

2) Select Issuing Agency for your UDIs and label your device with UDI

- Presently three FDA Accredited Issuing Agencies to choose from
  - GS1
  - HIBCC
  - ICCBBA

- Place the UDI in human readable (Plain Text) and machine readable (AIDC) on label and packaging, and for certain devices, on the device itself.

3) Determine GUDID Submission Option

- **Primary submission option – GUDID Web Interface or HL7 SPL?**
  - Ability to submit records via one option and edit via another after-DI-record-grace-period
  - Develop SOPs for record keeping

- **If necessary, identify a third-party submitter -- company/individual authorized to submit to GUDID on behalf of the labeler**

4) Gather Device Identification Data

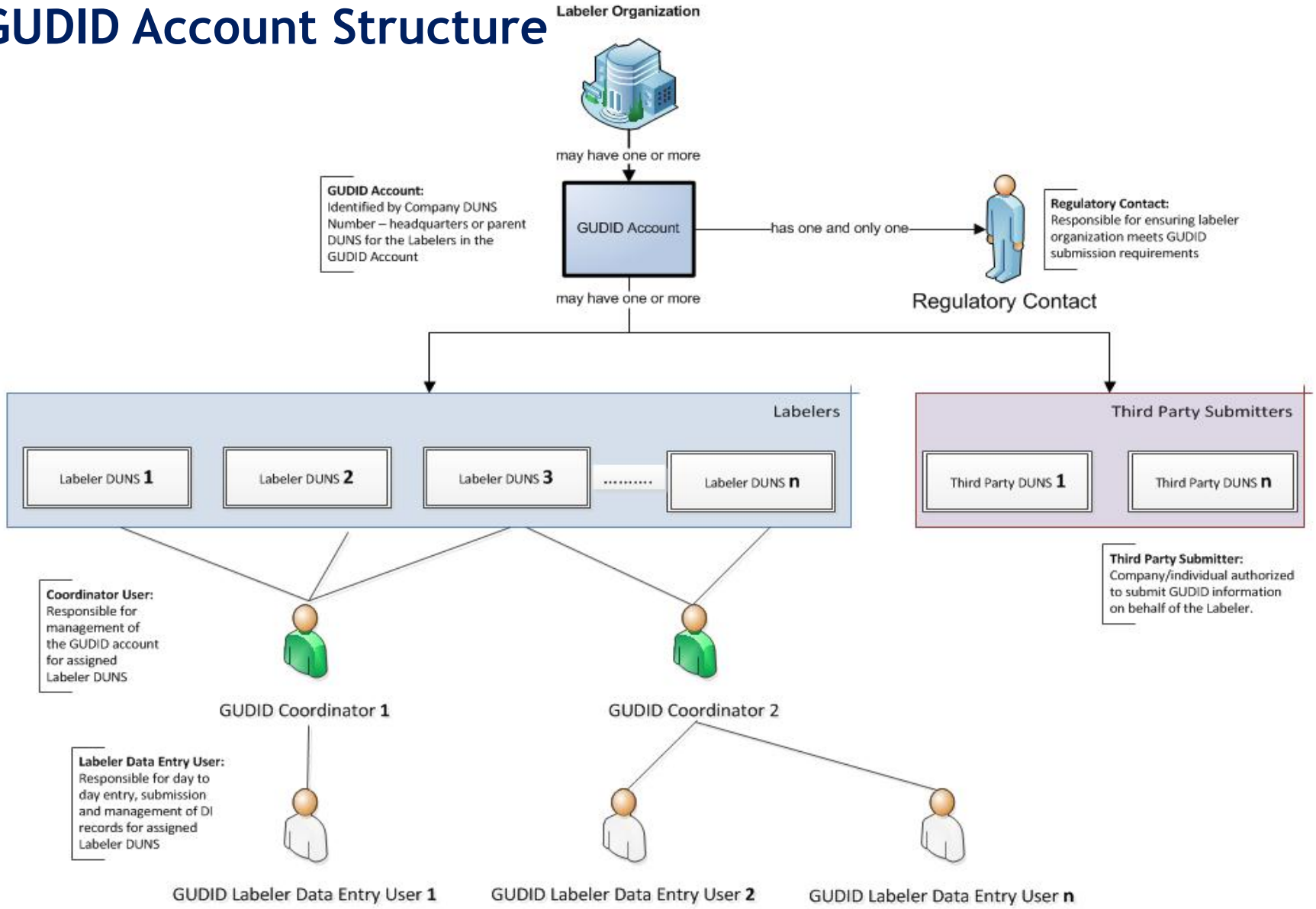
- **Attribute list in Data Elements Reference Table**
- **Global Medical Device Nomenclature (GMDN) Preferred Terms - *Required**
  - Identify/obtain active GMDN preferred terms for your devices, www.gmdnagency.org
- **FDA Listing Number - *Required**
  - Identify/obtain correct Listing Number for your devices
- **"Bake-in" data quality processes**

5) GUDID Account – TO DO

- GUDID Account is needed for submission of device information to GUDID
- Understand GUDID Account structure and User Roles
- Identify individuals for the different GUDID User Roles
- Ensure they understand GUDID functionality and responsibility for their user role

Note: You need a GUDID Account regardless of the submission option you choose.

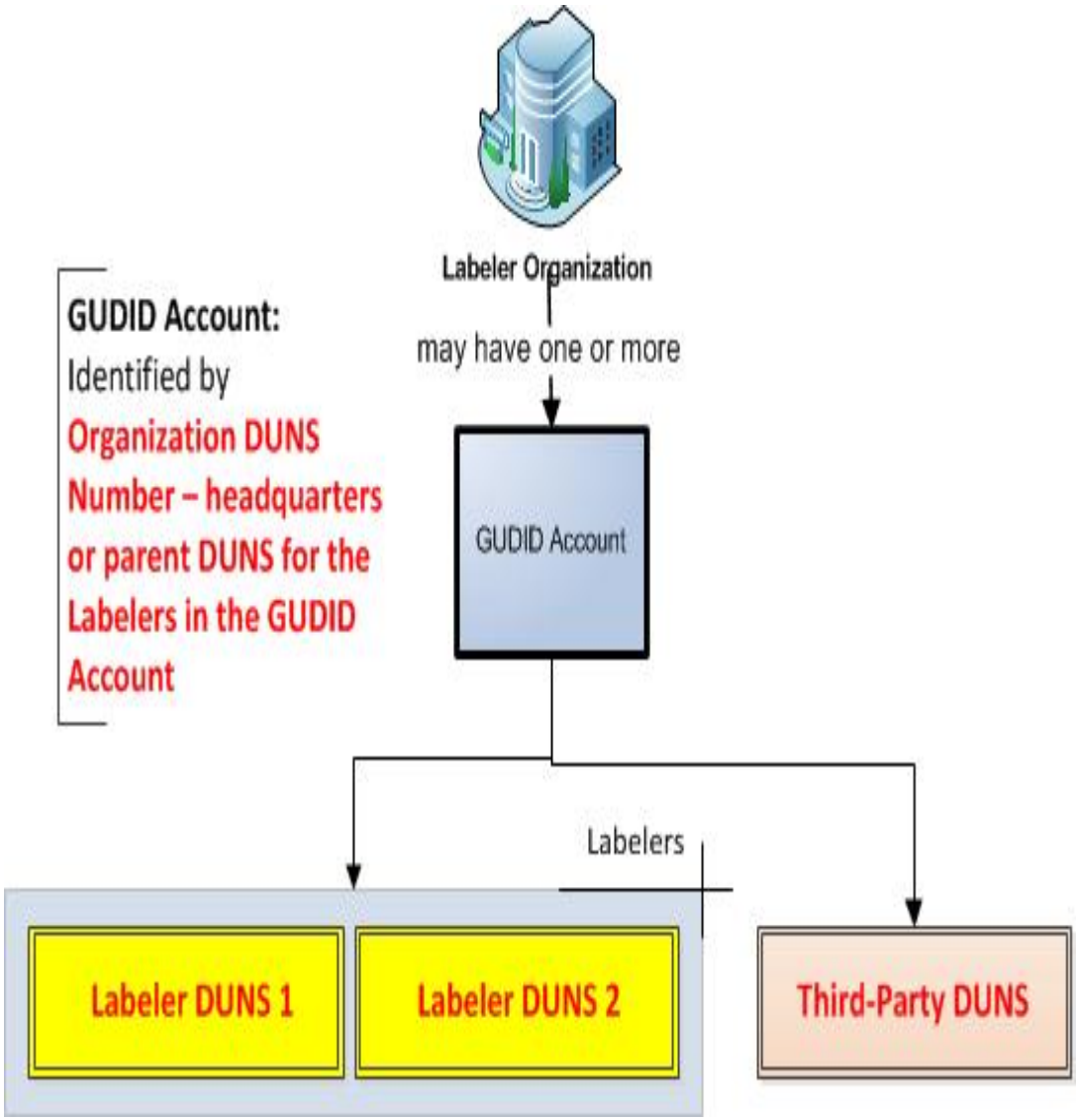
GUDID Account Structure



6) Identify/Obtain DUNS Numbers

- DUNS = Data Universal Numbering System
- 9 digit number assigned by Dun & Bradstreet
- DUNS Numbers are used to identify labeler organizations in GUDID
- Labeler name and address pulled from DUNS database
- http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162544.htm

DUNS Numbers in GUDID



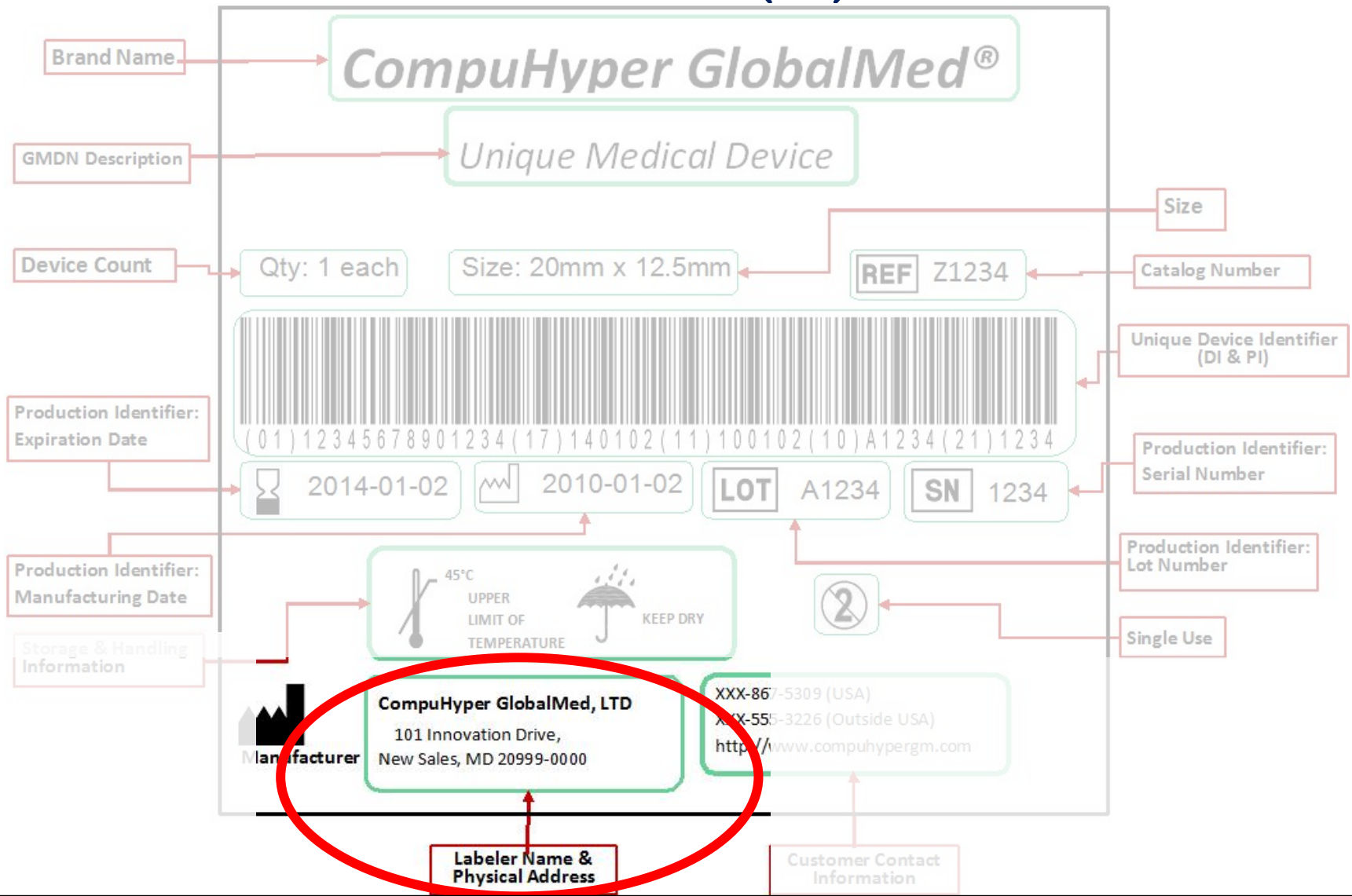
Organization DUNS - identifies the labeler organization for a GUDID Account

Labeler DUNS - identifies the Labeler as shown on the medical device label

Third-Party DUNS - identifies the individual/company authorized to submit information to GUDID on behalf of labeler

DI Record

DI Record = Device Identifier (DI) + GUDID attributes



7) Web Interface Submitters – TO DO

- **Request and obtain a GUDID Account**
  - No required testing
  - Request a GUDID Account, www.fda.gov/udi
- **Get familiar with the system**
  - Create Draft DI records
  - May submit DI records with a "future" publish date, i.e., Unpublished DI records – not available via public search
- **Submit and publish DI Records**

8) HL7 SPL Submitters – TO DO

- **Register with the FDA ESG and complete ESG testing**
  - Existing test accounts can be used
- **Request a GUDID Test Account, www.fda.gov/udi**
- **Complete HL7 SPL testing**
  - Test thoroughly, listed test scenarios are the bare minimum
- **Request and obtain a GUDID Account for production submission**
- **Submit DI records**
  - Note: "Draft" DI Record state is not available via HL7 SPL

Third-Party Submitters – TO DO

- **Verify information in the DUNS database is correct; update if needed**
- **May test HL7 SPL submission option independently of Labelers**
  - Request a GUDID Account, www.fda.gov/udi - indicate it is for HL7 SPL testing
  - Dummy data for certain required attributes will be provided for testing purposes ONLY, upon request

9) Subscribe for GUDID System Status

- Subscribe to GUDID Email Alerts 
- Scheduled downtimes -- email alerts sent and posted on www.fda.gov/udi, GUDID System Status
- Unscheduled downtimes
  - Visit www.fda.gov/udi for information
  - If no information, report issue via Help Desk

GUDID Status

- **Accepting submissions from Labelers of:**
  - Class III medical devices
  - Devices licensed under the PHS Act
  - Life Supporting/Life Sustaining/Implant devices – open **Monday, Jan 26, 2015**

- **GUDID Search and Retrieval targeting Spring 2015 for availability**

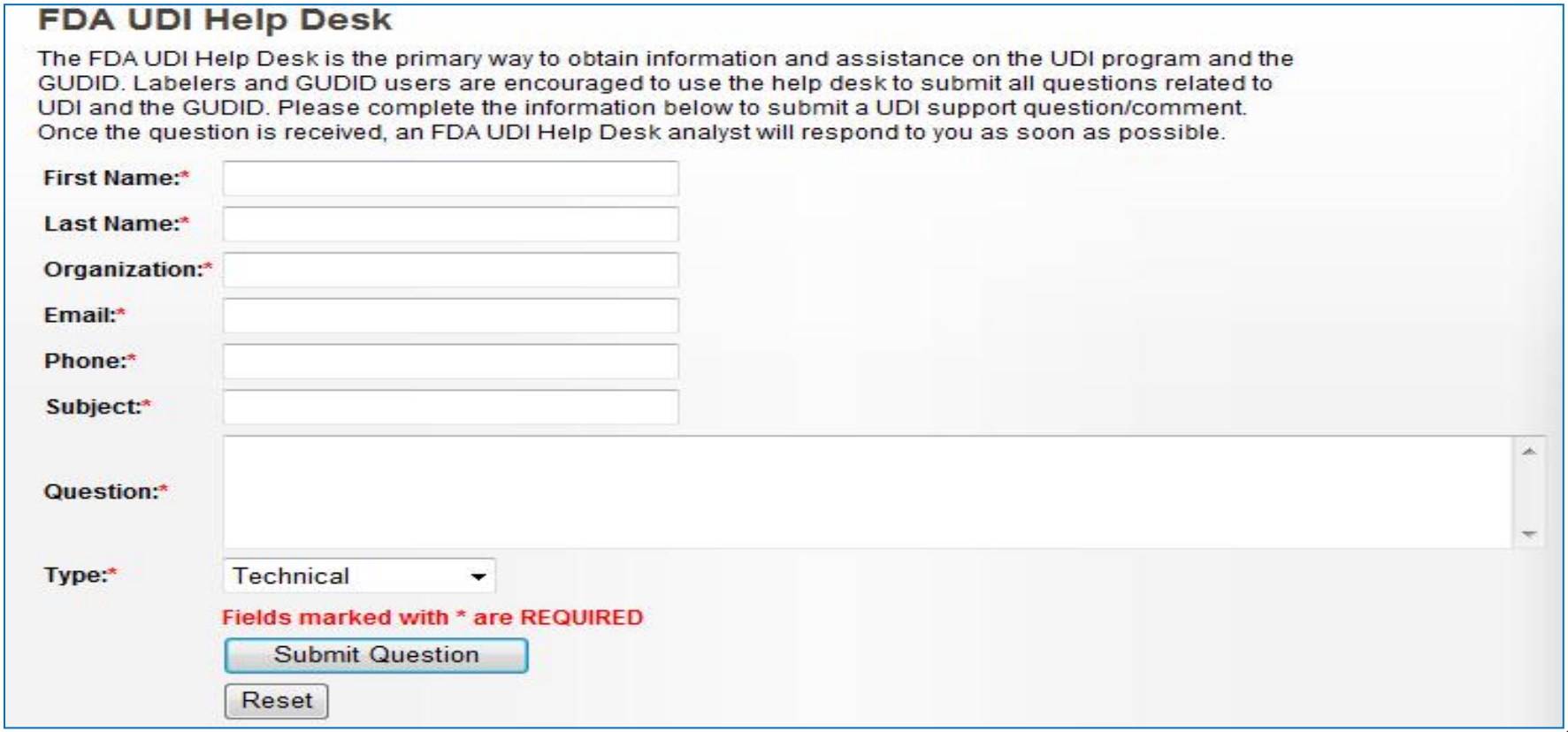
How to Contact Us

- HL7 SPL submitters with FDA ESG questions
  -- ESGHelpDesk@fda.hhs.gov

- All other inquiries via FDA UDI Help Desk
  - Regulatory questions
  - Technical questions

FDA UDI Help Desk

- Submit question via the web, www.fda.gov/udi
- Please complete all fields on the web form!



FDA UDI Help Desk

The FDA UDI Help Desk is the primary way to obtain information and assistance on the UDI program and the GUDID. Labelers and GUDID users are encouraged to use the help desk to submit all questions related to UDI and the GUDID. Please complete the information below to submit a UDI support question/comment. Once the question is received, an FDA UDI Help Desk analyst will respond to you as soon as possible.

First Name:*

Last Name:*

Organization:*

Email:*

Phone:*

Subject:*

Question:*

Type:* Technical

Fields marked with * are REQUIRED

Submit Question

Reset

FDA UDI Help Desk

- Question becomes a "case" in help desk tool
- Response will be sent to the email you provide
  - Ask follow-up questions by responding to the email, will append to the "case"

- Please ensure you can receive emails from help desk – check your spam folder

We are here to help!

- **Please submit complete and correct information**
  - Help Desk questions
  - Account Requests
  - DI Records
  - Build data quality into all tenets of your process as you get organized for GUDID submission

Questions?

FDA UDI Help Desk:
www.fda.gov/udi

Slide Presentation, Transcript and Webinar Recording will be available at:
www.fda.gov/CDRHWebinar

Under Heading: Unique Device Identification (UDI) System